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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,298	09/25/2000	Saleem Ahmad	HA0744 NP	2733
23914	7590	03/16/2004	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			LIU, HONG	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/669,298

Applicant(s)

AHMAD ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-10,14,15,17,19,20,22,24-31 and 63-74 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 28-30 and 63 is/are allowed.
- 6) ☒ Claim(s) 1-3,8-10,14,15,17,19,20,22,24,25,31 and 64-73 is/are rejected.
- 7) ☒ Claim(s) 26,27 and 74 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-3, 8-10, 14, 15, 17, 19, 20, 22, 24-31, and 63-74 are pending in this application.

This action is in response to the applicants' amendment and reply filed on December 29, 2003.

Response to Arguments

Applicants' arguments filed on December 29, 2003 have been fully considered but they are not persuasive. Rejection of claims under 35 U.S.C., first and second paragraph is maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Liras et al is hereby withdrawn in view of applicants' amendments of the definition of Z to be diaminopyridmidine.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 8-10, 14, 15, 17, 19, 20, 22, 24, 25, 31, 64-73 are rejected under 35

U.S.C. 102(e) as being anticipated by Almario-Garcia et al., Chem Abstract

135:257261. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compound having RN 362467-49-0 and 362467-50-3, i.e., R1 is substituted pyrimidine, Z is imidazole attached at its 4- or 5- position to the ring.

Claim Rejections - 35 USC § 103

The rejection of claims 1-3, 6, 8-10, 14, 15, 17, 22, 24-27, 31 63-76 under 35 U.S.C. 103(a) as being unpatentable over Stokbroekx et al. (WO 97/26258) is hereby withdrawn in view of applicants' amendment, which deleted pyridazinyl from the definition of R1.

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Claims 1-3, 8-10, 14, 15, 17, 19, 20, 22, 24, 25, 31, 64-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almario-Garcia et al. (EP 1136489). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, page 3 wherein R1 a heterocyclic ring having 1-4 hetero atoms, R2 represents a pyridyl ring, etc. The compounds are taught to be useful as pharmaceutical agents. Compounds in Table 1 on page 9 differs from the instantly claimed compounds only in nature of Z. However, the reference teaches the equivalence of a imidazole ring, phenyl, indole etc. It would have been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 112

The rejection of the word "prodrug" under 35 U.S.C. 112, first paragraph is maintained. In addition, the definition of "prodrug" in the specification is inadequate in that it does not provide any guidance for one skilled in the art on how the prodrug is converted to active compounds, by what mechanisms and at what site the prodrug will be activated, what in

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vivo enzymes are likely involved in cleaving the protected group, etc. The compound claims containing the word "prodrug" and the method claims are still not enabled for the same reasons given in the Final Office Action.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 14 and all its dependent claims recite the limitation of the zigzag symbol which has been changed to a line. The meaning of the line is not understood. There is insufficient antecedent basis for this limitation in the claim. In addition, it is unclear what constitutes the linker defined by the zigzag symbol. In addition, where is the Z of claim 1 in these formulas.

Claim 2 depends from a canceled claim.

The connectivity of the benzimidazole formula on page 3 of the Applicants' Response is not clear.

Allowable Subject Matter

Claims 28-30 and 63 are allowable. None of the prior art of record nor a search in the pertinent art area teaches the exact species of these claims.

2.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (571) 272-0669. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisors, Mukund Shah can be reached at (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 358-1235.


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624

hl
March 8, 2004